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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

KRISTIE PAGAN, ESTHER ALEXANDER, BRIDGETT HERRERA, VELICIA MATA, and ASHLEY SULLIVAN, individually and as parents and natural guardians of their minor children and on behalf of all others similarly situated,

Plaintiffs,

- against -

ABBOTT LABORATORIES, INC.,

Defendant.

2:10-cv-04676-ADS-WDW

DEFENDANT ABBOTT LABORATORIES, INC.'S SUR-REPLY IN OPPOSITION TO PLAINTIFFS' MOTION FOR CLASS CERTIFICATION

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Defendant Abbott Laboratories, Inc. ("Abbott") respectfully submits this sur-reply in opposition to Plaintiffs' class-certification motion (Dkt. No. 49).

PRELIMINARY STATEMENT

As Abbott has explained, Rule 23 "does not set forth a mere pleading standard"; a plaintiff "must affirmatively demonstrate" that all of its requirements are met. *Wal-Mart Stores, Inc. v. Dukes*, 131 S. Ct. 2541, 2551 (2011). To do so, Plaintiffs may not rest on the unsworn allegations in their complaint, *Szabo v. Bridgeport Machs., Inc.*, 249 F.3d 672, 675 (7th Cir. 2001), but must instead establish each Rule 23 requirement with "evidence" – i.e., "affidavits, documents, or testimony." *In re Initial Pub. Offerings Sec. Litig.*, 471 F.3d 24, 41 (2d Cir. 2006); *see also Teamsters Local 448 Freight Div. Pension Fund v. Bombardier Inc.*, 546 F.3d 196, 202-03 (2d Cir. 2008) ("preponderance of the evidence" standard applies). None of Rule 23's requirements is ever "presumed" satisfied. *Dukes*, 131 S. Ct. at 2551.

Plaintiffs' bare-bones opening memorandum cited no evidence, and as such, failed to meet Plaintiffs' burden under Rule 23. On reply, Plaintiffs attempt to salvage their case for certification by introducing ten new documentary exhibits and making a variety of new factual allegations. Some of these new exhibits are self-evidently irrelevant, and most of these new factual allegations lack any citations to the record; the Court therefore need not consider them. However, Abbott submits this sur-reply to correct several of Plaintiffs' most egregious misstatements and mischaracterizations.

ARGUMENT

I. As To Abbott's Alleged Failure To Disclose Information To The FDA

For the past year of discovery, Plaintiffs have searched in vain for evidence to support their allegation that Abbott "intentionally failed to advise the FDA . . . of the infestation of Warehouse Beetles . . . at the Sturgis facility." (Second Am. Compl. ¶ 66.) The uncontradicted evidence is that Abbott provided *all EcoLab pest control records* to the United States Food and Drug Administration ("FDA") between 2007 and 2010, and that the FDA found "no significant deficiencies" with the Sturgis facility – including its pest control – prior to the recall. (Painter Decl. (Exhibit to Abbott's Reply Mem. Regarding Mootness (Dkt. No. 43)) ¶¶ 30, 32; Painter Dep. (Ex. A to Winter Decl. (Dkt. No. 55)) at 38:19-40:24; 64:23-65:23; 66:24-67:1; 127:7-18.)

Plaintiffs' reply resorts to fabrication, stating that "[d]espite FDA requests therefor, ABBOTT failed to turn over EcoLab Pest control audits for the period April 23, 2010 through September 16, 2010." (Reply Mem. at 3.) In support of this serious assertion, Plaintiffs cite only the FDA's Form 483 Report setting forth its post-recall "inspectional observations." That report says *nothing* about any "fail[ure] to turn over EcoLab Pest control audits" or any other failure to cooperate. To the contrary, the FDA announced in October 2010 that "Abbott ha[d] worked with . . . FDA officials to satisfactorily implement plans at [the Sturgis] facility to correct the situation, and prevent its recurrence." (Winter Decl., Ex. D.)

The apparent genesis of Plaintiffs' claim that Abbott withheld EcoLab reports "for the period April 23, 2010 through September 16, 2010" is the fact that the FDA's Form 483 Report happens not to cite any EcoLab reports from this five-month interval. (Reply Mem., Ex. C at ABT-SIM00183822.) It is brazen enough that, at this late stage, Plaintiffs allege intentional concealment based solely on this innocuous observation. It is worse that Plaintiffs repeat this allegation as fact *after it was expressly debunked* at the deposition of the Sturgis plant's former Quality Assurance Manager, Matthew Painter:

> Q: Do you know why there was a gap in [EcoLab] reports between 4/23/10 and 9/17/10?
>
> A: *There was no gap in EcoLab reporting.* They reported, every week, the counts from every single light trap.
>
> * * *

Q: Except that the question is, why was the FDA then not given the reports from May, June, July, and August of 2010?

A: *They were. They were given all of them.*

Q: Well, do you have any understanding why those months are eliminated from . . . the [FDA's] Form 483?

A: I don't know why they were not included.

* * *

Q: All right. So you don't know the reason why those months were eliminated from . . . the Form 483, correct?

A: Correct. I don't know. The – *again, we provided all of our reports –*

Q: Okay.

A: *– throughout that period.*

(Supplemental Excerpts of Dep. of Matthew Painter (Ex. A hereto) at 178:17-180:6 (emphasis added).) On cross-examination, Mr. Painter again testified:

Q: . . . [T]his is the Form 483 that the FDA issued; is that right?

A: Yes.

* * *

Q: And there was a gap, I believe, on Exhibit 8 between 4/23/10 and 9/17/10 where there are no [EcoLab] observations noted in Exhibit 8; is that correct?

A: There are no observations noted there, yes.

* * *

Q: *And it's your testimony that you did provide all EcoLab records to FDA, including records generated during the period of that gap, correct?*

A: *Yes.*

Q: And for whatever reason, FDA didn't put it in their Form 483, correct?

A: That's correct.

(*Id.* at 232:8-233:23 (emphasis added).)

Mr. Painter's testimony is unambiguous, unimpeached, and uncontradicted. In light of this, Plaintiffs' claim that Abbott withheld requested records from the FDA – and Plaintiffs' failure to inform the Court that the only evidence in the record states the opposite – tests the limits of ethical argument.

II. As To The Percentage Of Recalled Units That Contained Beetles

As Abbott explained in its opposition memorandum, in connection with the recall, Abbott personnel filter-tested 30,486 containers from over 20 separate lots of powdered Similac manufactured at Sturgis in the three months preceding the recall. (Painter Decl. ¶ 23; Ex. A thereto at 35; Ex. J thereto.) Across those 30,486 containers, a total of 49 beetles, larvae, and/or parts thereof were detected – *a rate of only 1 per 625 containers tested, or 0.16%*. (*Id.* ¶ 24 & Ex. J and K thereto.)

In their reply memorandum, Plaintiffs state the following:

> [In its recall-related testing,] ABBOTT found adult beetles and larvae in eight (8) of the twenty one (21) lots it sampled. This staggering figure constitutes 38% of the total tested. Statistically, if all recalled units had been tested, a projected 44.5 million units [i.e., 38% of the total recalled units] . . . would have tested positive for adult beetle and larvae content.

(Reply Mem. at 2.) Plaintiff cite no evidence for these figures. In any event, Plaintiffs' conclusion is a non-sequitur for two reasons.

First, every "lot" contains *thousands of individual units*. (Painter Decl. ¶¶ 22-23; Ex. A thereto at ABT-SIM00031875, ABT-SIM00031909; Ex. J thereto; Second Am. Compl. ¶ 30.) The presence of at least one beetle or larva in 38% of tested *lots* does not imply the presence of beetles in 38% of "all recalled *units*."

Second, the record is devoid of evidence that beetles were present *in any* lots of finished Similac product manufactured before July 2010. (Painter Decl. ¶ 30; Painter Dep. at 35:7-13; 58:2-8.) Plaintiffs fault Abbott for "not gather[ing] test data" on lots manufactured prior to July

2010 (Reply Mem. at 2), but it is Plaintiffs' burden to prove commonality, not Abbott's burden to *disprove* it. *See Brandner v. Abbott Labs., Inc.*, No. 10-3242, 2012 WL 195540, at *4-*5 (E.D. La. Jan. 23, 2012) ("Although [Plaintiffs' expert] criticizes Abbott for testing a small sample, . . . [Plaintiff], not Abbott, has to establish contamination of the recalled units . . . by common proof to certify a [class].").

III. As To The Numerosity Of The Proposed Classes

Plaintiffs seek to represent classes comprised of all New York and New Hampshire residents "who *purchased* SIMILAC products subject to the recall." (Second Am. Compl. ¶¶ 81, 83 (emphasis added).) Plaintiffs' opening memorandum cited *no* evidence of the number of end-consumers in New York and New Hampshire who spent money on recalled Similac; instead, it merely proclaimed that "Plaintiffs . . . estimate at least several hundred thousand putative class members . . . ." (Opening Mem. at 14.)

Belatedly realizing that, after *Dukes*, numerosity may not be "presumed," Plaintiffs now submit Abbott's responses to interrogatories propounded on the eve of the filing of their class-certification motion. Those responses state that "182,092 end-consumer recall-notification letters were mailed . . . to residential addresses in the state of New York and 16,893 end-consumer recall-notification letters were mailed . . . to residential addresses in the state of New Hampshire." (Reply Mem. at 6 (emphasis omitted).) Even if the Court is inclined to entertain this new evidence, it does not establish the numerosity of the proposed classes.

The only thing that these figures show is the number of letters that Abbott mailed to addresses in New York and New Hampshire notifying individuals of the recall. Nothing in the record establishes the percentage of these letters that were sent to actual *purchasers* of recalled units of Similac. Indeed, as Abbott's Director of Consumer Relations testified, "the vast majority of recipients" of these letters "were not on [Abbott's mailing] list because they necessarily purchased [Similac] for money," but instead were "recipients [of] free samples" in Abbott's marketing database. (Dep. of Laurie Boogaard (Ex. C to Winter Decl.) at 169:11-170:13.) The receipt of a free Similac sample does not qualify an individual for membership in Plaintiffs' proposed classes. Thus, even if the Court considers the figures submitted with their reply, "Plaintiffs have not presented the court with any specific evidence that there are any other persons" besides themselves who satisfy their class definition. *Pelman v. McDonalds Corp.*, 272 F.R.D. 82, 99 (S.D.N.Y. 2010).

But that is not the end of the matter. The number that is actually relevant to certification is not the number of New York and New Hampshire residents who bought recalled Similac, as Plaintiffs would have it, but rather, the far smaller number of New York and New Hampshire residents who allegedly "suffered the same injury" as Plaintiffs. *Dukes*, 131 S. Ct. at 2551 (noting that "the class members [must] 'have suffered the same injury'" and "not . . . merely . . . a violation of the same provision of law"); *see also Pelman*, 272 F.R.D. at 99.

As already discussed, virtually all recalled Similac units were defect-free. Thus, Plaintiffs have not come close to "affirmatively demonstrat[ing]," by a preponderance of the evidence, that the number of New York and New Hampshire Similac purchasers who "suffered the same injury" they allegedly did is so numerous that joinder of all members is impracticable. *Dukes*, 131 S. Ct. at 2551; *accord Pelman*, 272 F.R.D. at 99 (numerosity not shown where "Plaintiffs have not yet established that there are any other persons . . . who were exposed to the [allegedly deceptive] marketing at issue, then regularly ate at McDonalds, *and subsequently developed the same medical injuries as those allegedly suffered by Plaintiffs*" (emphasis added)).

IV. As To Abbott's Pre-Recall Standard Operating Procedures

For the first time on reply, Plaintiffs level a variety of criticisms at Abbott's pre-recall "Standard Operating Procedures ('SOP')," which Plaintiffs allege were "either non-existent or woefully deficient." (Reply Mem. at 4.) There are several problems with this argument.

One, rather than citing Abbott's allegedly deficient pre-recall SOPs (which were produced during class discovery), Plaintiffs cite two *post-recall* documents listing "update[s]" made to Abbott's SOPs "[t]o better identify and respond to signals of potential pest activity in the [Sturgis] plant." (Reply Mem., Exs. G-H.) It is fundamental that "[w]hen measures are taken that would have made an earlier injury or harm less likely to occur, evidence of the subsequent remedial measures is not admissible to prove[] negligence; culpable conduct; a defect in a product or its design; or a need for a warning or instruction." Fed. R. Evid. 407.

Two, these documents do not support the propositions for which Plaintiffs cite them. For example, Plaintiffs' exhibits show that, post-recall, Abbott placed a firm deadline in its SOPs that "actions associated with pest control inspections [be completed] *within ten calendar days*." (Reply Mem., Ex. G (emphasis added).) However, this does not support Plaintiffs' contention that, before the recall, "[t]here was *no* requirement for completing actions associated with pest control inspections." (Reply Mem. at 4 (emphasis added).) Plaintiffs' exhibits show that, post-recall, "[a] fixed schedule for pest control treatments" was codified in Abbott's SOPs. (Reply Mem., Ex. G.) But that does not imply that, before the recall, "ABBOTT did not have a fixed schedule for pest control treatments." (Reply Mem. at 4.) Plaintiffs' exhibits show that, post-recall, Abbott's SOPs were updated with "[a] requirement for *quarterly reviews* with department management regarding pest control." (Reply Mem., Ex. G (emphasis added).) This does not imply that, before the recall, "[t]here was *no* management oversight" of pest-control decisions.

(Reply Mem. at 4 (emphasis added).) Plaintiffs' exhibits show that, post-recall, Abbott's SOPs were modified to "include specific instructions . . . to document any evidence of pests" *on a particular form* called a "'Plant Information Report' (PIR)." (Reply Mem., Ex. H.) This does not imply that, before the recall, Abbott "did not provide for documentation of pest levels." (Reply Mem. at 5; *cf. id.*, Ex. E (documenting pre-recall insect activity on a different form).)

Finally, even assuming Abbott's pre-recall pest-control protocols were insufficiently robust, it remains unclear how this establishes a shared class-wide injury.

V. As To Abbott's Reduction Of Its Inventory Of Recalled Products

For the first time, Plaintiffs cite as "evidence" of Abbott's purported consumer fraud the fact that "ABBOTT has obtained judicial approval [to] destroy[]" all Similac returned pursuant to the September 2010 recall, except for a representative sample of over 100,000 units.

Plaintiffs cannot criticize Abbott's inventory reduction at this late date. It was approved in August 2011 by Magistrate Judge Wall with no opposition from Plaintiffs. (*See* Dkt. No. 25 at 2 (finding inventory reduction justified in light of the "unnecessary expense . . . of storing such a huge inventory, the potential spoilage and attendant health concerns, the FDA's urging that the product be destroyed, and the adequacy of a representative sample as evidence").) Plaintiffs did not seek reconsideration of that order. Furthermore, Abbott's inventory reduction has been unanimously approved by eight other district courts. (*See* Order in *Knipe v. Abbott Labs., Inc.* (Ex. B hereto) (identifying courts that have approved inventory reduction and agreeing that "[Abbott's] proposed retention of over 100,000 units is more than sufficient to adequately test the characteristics of the entire population of recalled products").)

It bears noting that Plaintiffs made no attempt to examine or test any of the 100,000 representative units that Abbott has preserved pursuant to these courts' orders, even though

Plaintiffs bear the burden of establishing commonality and predominance.

VI. As To Plaintiffs' "Price Premium" Theory Of Injury

For the first time on reply, Plaintiffs cite several cases that have allowed § 349 claims to proceed where the plaintiff alleged that she "paid a premium" for a product based on a representation that it had a characteristic or quality the plaintiff did not receive. (Reply Mem. at 7-8.) However, in each of the cases Plaintiffs cite – all of which are decisions on motions to dismiss, and none of which are decisions certifying class actions – the plaintiffs alleged that the sellers' statements were false *in their own personal experience.*

For example, in *Jernow v. Wendy's Int'l, Inc.*, the plaintiff stated a § 349 claim by alleging that he paid a premium for food that was falsely advertised as "trans fat-free," and that this deception personally caused him to "ingest[] foods that contained unsafe amounts of trans fats," depriving him of the health benefit he had paid extra for. No. 07 Civ. 2971, 2007 U.S. Dist. LEXIS 85104, at *7-*9 (S.D.N.Y. Nov. 15, 2007) (acknowledging that the "allegations of injury [were] weak"). In *Ackerman v. Coca-Cola Co.*, the plaintiff stated a § 349 claim by alleging that she purchased a unit of "Vitaminwater" whose labeling "suggest[ed] that [it] contain[ed] nothing but vitamins and water," when that very unit contained a "significant amount of sugar," again depriving her of the health benefits for which she paid a premium. No. CV-09-0395, 2010 U.S. Dist. LEXIS 73156, at *17-*18 (E.D.N.Y. July 21, 2010). In *Rodriguez v. It's Just Lunch, Int'l*, the plaintiff stated a § 349 claim by alleging that she paid a premium for a dating service because it promised to match her "strictly with other professionals" and provide "at least six dates," but only provided her four dates, including one with a non-professional. No. 07 Civ. 9227, 2010 U.S. Dist. LEXIS 16622, at *6-*7 (S.D.N.Y. Feb. 23, 2010).

The most that these cases arguably establish is that Plaintiffs might prevail on their individual claims by proving (1) that they paid a "premium price" for Similac specifically on account of Abbott's alleged promise of "safe[ty]" (a statement which Plaintiffs now concede they did not actually see (Opp. Mem. (Dkt. No. 56) at 22)), and (2) that the particular Similac units they purchased were not in fact "safe." However, there is no legitimate dispute that approximately 99.9% of recalled Similac units *were* "safe," and that 99.9% of the putative class members received exactly what they ostensibly paid a "premium price" to receive.

Plaintiffs cite no case in which a consumer who *did* receive what she bargained for was allowed to bring a consumer-fraud claim merely because *other* units in the same product line were defective. Nor do Plaintiffs cite any case certifying a class consisting of all purchasers of a given product line where the manufacturer's representations were false, at most, only as to a handful of individual units of product. Myriad cases have dismissed consumer-fraud claims and refused to certify consumer-fraud classes under those circumstances. (*See* Opp. Mem. at 12-14, 18-20, 24.) Thus, Plaintiffs' "price premium" theory cannot provide the "glue holding [the putative class members' claims] together." *Dukes*, 131 S. Ct. at 2552.

CONCLUSION

For the reasons set forth above, and in Abbott's opposition memorandum (Dkt. No. 56), Abbott respectfully requests that the Court deny Plaintiffs' motion for class certification.

June 5, 2012

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